

REMARKS

Claims 1-7, 10, 11, 15-22, 25-31, 33, 34, 36, 37, 39-43, 45, 46, 48-51, 53-56, 58, 59, 61, 62, 64, 65, 67-69, 71, 72, 74-76, 78, 80, 81, 83-101, 103, and 104 are currently pending.

Applicants note that the Examiner has not listed claims 84-98 and 104 as pending claims.

Applicants request clarification.

Claims 1-7, 10, 11, 15-22, 25-31, 33, 34, 36, 37, 39-43, 45, 46, 48-51, 53-56, 58, 59, 61, 62, 64, 65, 67-69, 71, 72, 74-76, 78, 80, 81, 83, 99-101, and 103 are subject to a restriction requirement under 35 U.S.C. §121. The Examiner has required the Applicants to elect one of the allegedly distinct inventions, classified as Groups I-IV. Reconsideration of the restriction requirement in view of the following remarks is respectfully requested.

Applicants request entry of the additional amendments to the claims, as described below.

Claims 1, 2, 42, 50, 55, 99, and 100 have been amended to replace “derivative” with “salt” in the phrase “or as a pharmaceutically acceptable derivative thereof”. Support for this amendment can be found on page 12 of the specification.

Claims 1, 99, and 100 have been amended to delete an inadvertent “)” after $-N(R^8)R^9$ in the definition of R^4 and R^5 .

Claims 1, 2, 99, and 100 have been amended to clarify that Q^1 and Q^2 are directed to, *inter alia*, the $-O-(CH_2)_y-O-$, $-S-(CH_2)_y-O-$, and $-S-(CH_2)_y-S-$ groups.

Claim 2 has been amended to become an independent claim. Support for the amendment can be found on page 27, line 15 through page 34, line 9.

Claim 3 has been amended to delete an inadvertent apostrophe in the definition of R^2 .

Claim 3 also has been amended to bring the R^{5a} group in conformity with claim 2. Support for two adjacent R^{5a} groups forming an phenyl group such that R^5 is naphthyl can be found in R^5 of original claim 2 and in the definition of “aryl”, on page 20, lines 14-17. Support for a 5-6 membered heteroaryl ring can be found in R^5 of original claim 2 and in the definition of “heteroaryl”, on page 20, lines 18-25. Support for the $O-(CH_2)_y-O-$, $-S-(CH_2)_y-O-$, and $-S-(CH_2)_y-S-$ groups can be found in Q^1 of original claim 2.

Claim 4 has been amended to bring the R^{1a} group in conformity with claim 2.

Claim 5 has been amended by: a) deleting the first compound for improper antecedent basis, and inserting it at the end of claim 7; and b) deleting the 52nd and 53rd compounds for improper antecedent basis; both compounds are claimed in original claim 17.

Claim 7 was amended by deleting the 16th, 21st, 38th, and 48th compounds for improper antecedent basis and adding them to new claim 105. The 17th and 59th compounds have been deleted.

Claims 15, 26, 42 have been amended in a manner similar to claim 3.

Claim 26 has been amended by: a) replacing “alkylene” with “C₆ cycloalkyl”, support for which can be found on page 19, line 30; b) replacing “alkenylene” with “phenyl”, support for which can be found in R⁵ of original claim 2 and in the definition of alkenylene on page 23, lines 19-21; and c) replacing “alkylenedioxy, thioalkylenoxy, or alkylenedithioxy” with “-O-(CH₂)_y-O-, -S-(CH₂)_y-O- or -S-(CH₂)_y-S-, where y is 1 or 2”, support for which can be found on page 10, lines 7-8.

Claims 29, 51 have been deleted.

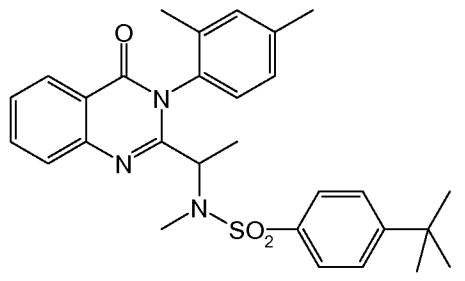
Claims 43, 50, 55, 56, 59, 62, 65, 69, 72 has been amended to further clarify the invention.

Claims 75, 76, and 78 have been amended to bring the R⁴ and R⁵ groups in conformity with claim 1.

New claim 105 has been added, and it is directed to four compounds which were deleted from claim 7.

With respect to the restriction requirement, Applicants hereby elect Group I.

Applicants hereby elect the species 4-*tert*-butyl-*N*-(1-[3-(2,4-dimethylphenyl)-4-oxo-3,4-dihydroquinazolin-2-yl]ethyl)-*N*-methylbenzenesulfonamide (page 432, lines 13-14) for searching purposes:



Claims 1-7, 10, 11, 22, 25, 27, 28, 30, 31, 33, 34, 36, 37 , 39-43, 45, 46, 48-50, 83, 84-98, 99-101, 103, 104 (and new claim 105) encompass the elected invention.

The applicant's traverse of the restriction for the following reasons. Several claims are generic or linking claims (e.g., claims 1, 2, 3, 15, and 50). Accordingly, pursuant to MPEP §§ 803.02 and 809, the applicants respectfully request the Office expand examination of the claims to the non-elected portion of the generic claims, which, in the present instance, is the full scope of all claims.

As stated in MPEP § 809,

There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called 'linking' claims) which, if allowable, would require rejoinder of the otherwise divisible inventions. See MPEP § 821.04 for information pertaining to rejoinder practice. . . . The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are (A) genus claims linking species claims The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement must be withdrawn. Any claims(s) directed to the non-elected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

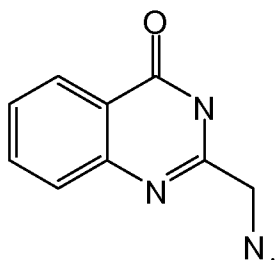
M.P.E.P. § 809 (emphasis added).

The applicants have the right to define what they regard as their invention, so long as their claims otherwise satisfy the statutory requirements. *In re Harnisch*, 206 U.S.P.Q. 300, 305 (C.C.P.A 1980). Applicants have the right to have each claim examined on the merits. *In re Weber et al.*, 198 U.S.P.Q. 328, 331 (C.C.P.A. 1978). Restriction of the subject matter of a single claim in a patent application is therefore generally impermissible because it denies the applicant the right to have that claim examined on the merits. *Id.* As the court stated in *Weber*, if "a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits." *Id.* Accordingly, "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." M.P.E.P. § 802.03.

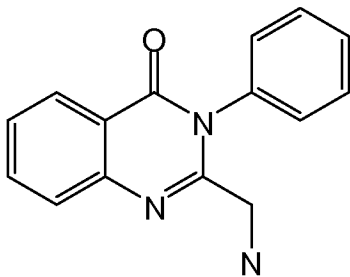
The claims are written in Markush format. A Markush grouping is proper if the compounds in the Markush group share a single structural similarity and a community of

properties (e.g., a common utility), such that the grouping is not repugnant to the principles of scientific classification. *Harnisch*, 206 U.S.P.Q. at 305; *Ex parte Brouard et al.*, 201 U.S.P.Q. 538, 540 (Bd. Pat. App. & Int. 1976). In other words, “unity of invention exists where compounds share a common utility, and (2) share a substantial structural feature essential to that utility.” M.P.E.P. § 802.03. The fact that the compounds in a Markush group may require different fields of search does not render the Markush group improper. *Brouard*, 201 U.S.P.Q. at 540. Also, where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by consideration of the compound as a whole, and does not depend on there being a community of properties among the members of the Markush expression. *Id*; *Harnisch*, 206 U.S.P.Q. at 305; M.P.E.P. § 2173.05(h). In *Harnisch*, 206 U.S.P.Q. at 305, and as it is applied in *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984), the determinative factor for determining whether or not a Markush group is proper was held to be whether there existed “unity of invention,” or rather whether the claims were drawn to a collection of unrelated inventions. Specifically, the claims in *Harnisch* were drawn to a class of substituted coumarin compounds disclosed as being “useful as dyestuffs.” 206 U.S.P.Q. at 305. Accordingly, all of the claims had in common a functional utility related to a substantial structural feature disclosed as being essential to that utility.

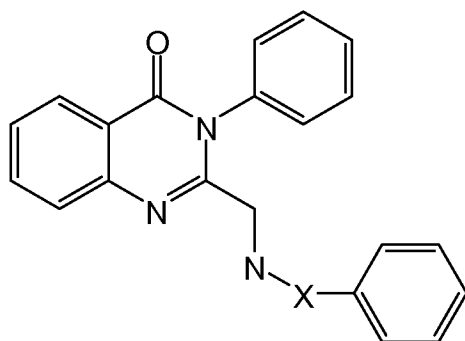
Applicants submit that each of the presently pending claims possesses unity of invention. First, all of the compounds share a common utility as modulators of FXR activity. Second, each of the compounds in the Markush groups share the common structure:



Furthermore, linking claims 2, 3, 15, and 50 (and those that depend from them) share an even greater structural similarity:



And linking claims 3, 15, and 50 (and those that depend from them) share still greater structural similarity:



where X is -C(O)- (structure IV) or $\text{-SO}_2\text{-}$ (structures II and IV). Accordingly, all of the compounds read upon by the claims share structural features essential to their utility as modulators of FXR activity.

Because the claims possess unity of invention, they are proper Markush claims and should be examined fully on their merits as generic linking claims for the elected group. To do otherwise would infringe on Applicants' "right to have each claim examined on the merits." *Weber*, 128 U.S.P.Q. at 331.

The proper procedure for examining Markush claims is provided in M.P.E.P. § 803.02:

A Markush-type claim may include independent and distinct inventions. ... In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. ... Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

* * *

On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Applicants hereby reserve the right to prosecute the claims encompassed by any of the non-elected groups in future divisional applications.

Applicants further traverse the Restriction Requirement on the grounds that no serious burden is placed on the Examiner if restriction is not required. As noted above, the claimed compounds have substantial structural features in common and are similarly categorized within the same set of classes and subclasses. Applicants submit that a search in the common class and subclasses do not constitute a serious burden on the patent office, particularly with the common structural core.

If it is believed that a teleconference will advance prosecution, the examiner is encouraged to contact the undersigned as indicated below.

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